Table 1

Dispute Issue #1

EPA June 22, 2012 letter:

"The discussion of the process used to evaluate risks to humans and the conclusions were not clearly presented and, in fact, there were several instances of incorrect or misleading information. For example, the BHHRA repeatedly stated that the exposure assessment assumed someone ate fish every day of the year for 30 years.

The LWG is fully aware that such a statement is not accurate. Consumption rates are average lifetime intake doses mathematically averaged to give an average daily rate. EPA commented on this issue in our February 9, 2010 comment letter; however, the LWG failed to address it."

LWG May 2, 2011 Revised Draft BHHRA language (Section 3.5.1.6.3, page 66):

"This rate corresponds to approximately 23 meals per month every month of the year of fish caught exclusively within the Study Area."

LWG May 2, 2011 Revised Draft BHHRA language (Section 5.2.5.2.1, page 98):

"These rates correspond to approximately 19 meals per month, 10 meals per month, and two meals per month, based on an 8-ounce serving size, every month of the year exclusively of resident fish caught within the Study Area."

LWG May 2, 2011 Revised Draft BHHRA language (Section 6.2.5.1, page 124):

"For the tribal fisher RME scenario, the exposure parameters are especially conservative as it is unlikely that an individual would fish the same ½-river mile river segment for five days every week of every year for 70 years."

LWG May 2, 2011 Revised Draft BHHRA language (Section 6.2.5.2, page 125):

"The tap water ingestion rate used in the risk evaluation was 2 L/day for the transient and assumes surface water will be ingested every day for two years."

"This scenario assumes untreated surface water is used as a domestic water source 350 days a year for 30 years (adult resident) or six years (child resident)."

LWG May 2, 2011 Revised Draft BHHRA language (Section 6.2.5.3, page 128):

"For example, fish consumption by an adult tribal fisher was assumed to occur at the same rate every day of every year for 70 years."

Discussion: See Deficiency #18. LWG in Table 1 admits to not correcting all instances. EPA's comment stated to correct all instances, not just those cited by EPA (see highlighted in Deficiency #18).

Proposed Resolution: EPA has corrected all instances in the document.

Dispute Issue #2a (Table 1)

EPA June 22, 2012 letter:

There were several instances where the BHHRA does not fully reflect EPA's directions for change, directions given years before and reiterated in our comments to previous versions. For example, EPA's February 2010 **[should be July 16, 2010]** comment on Section 3.4, page 31 was:

In this section and subsequently throughout the risk assessment, replace the term "95% UCL/max EPC" with "RME EPC." The repeated references to a "mean" EPC relative to one based on a 95 percent UCL or maximum concentration is misleading. The text in the second paragraph incorrectly states that exposure point concentrations would be calculated differently for central tendency (CTE) and reasonable maximum (RME) exposures. **Consistent with EPA guidance (1992, 2000), the EPC should represent an estimate of the arithmetic average concentration for a contaminant based on a set of site sampling data. Because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent UCL of the arithmetic mean should be used for this variable.** The 95 percent UCL provides reasonable confidence that the true site average will not be underestimated. The average concentration, defined as the 95 percent UCL, should be used for both CTE and RME evaluations. The RME evaluation should be distinguished from CTE by accounting for variability in such variables as exposure frequency and intake rates.

However, the LWG did not make the change, claiming that the EPCs were described in a factual manner. Use of the term 95% UCL/Max Scenario is incorrect and needs to be changed throughout the document. RME and CT are not defined based solely on calculation of EPC. Actually, EPC should be the same for both the RME and CT. Since the LWG used different EPCs for the RME and CT calculations, EPA is requiring the removal of the CT evaluations for the consumption scenarios in the BHHRA. Further, reference to RME and CT in the BHHRA were not consistent with those agreed to in the Programmatic Work Plan. EPA has modified the BHHRA to reflect those agreements and adequately describe the RME and CT.

Programmatic Work Plan, April 23, 2004, Appendix C, Section 3.5:

Rationale and/or references for each of the RME and CT values for exposure pathways that will be quantitatively assessed (with the exception of fish ingestion pathways) are provided in the

exposure factor tables for each receptor (Tables 5 through 14). Exposure factor values for fish ingestion are discussed in Section 3.5.1.4.

EPA March 15, 2004 letter:

Our review and comments have attempted to reconcile apparent inconsistencies in the Work Plan. However, since the main text and various appendices have gone through several revisions there may still be some inconsistent language and references in the document. Rather than take the time to re-check and resolve all of these issues, EPA prefers to move ahead with the Work Plan approval recognizing this limitation.

Programmatic Work Plan April 23, 2004, Appendix C, Section 3.5.1.4 (p. 32-33):

Resident Fish Species

Site-specific fish consumption information is not available for the recreational fisher or high consumption non-tribal fisher scenarios. Therefore, to evaluate the potential range in consumption patterns that may exist for these receptors, 3 ingestion rates will be used to calculate intakes for adults and 3 will be used for children. For adults, the fish ingestion rates that will be used in the HHRA are 17.5 grams per day (g/day), 73 g/day, and 142 g/day. The corresponding rates that will be used for children are 7 g/day, 31 g/day, and 60 g/day. These ingestion rates are anticipated to represent average to high end ranges of fish consumption for these receptors.

Two of these rates, 17.5 g/day and 142 g/day, represent the 90th and 99th percentile ingestion rates for freshwater and estuarine fish and shellfish for individuals (consumers and non-consumers) of age 18 and over in the United States (EPA 2002c). Because these rates are from a national dietary study, they may not be representative of site-specific consumption patterns. The other ingestion rate, 73 g/day, is from a creel study conducted in the Columbia Slough and is the 95 percent upper confidence limit on the average for ingestion of fish where 75 percent of the total fish is consumed (Adolfson 1996). While this study may be more representative of consumption patterns for the Site, the study was limited in scope and the reported ingestion rates were estimated based on numerous assumptions. The uncertainties associated with each of the fish ingestion rates will be discussed in the HHRA.

For the recreational fisher and high consumption non-tribal fisher scenarios, the risk assessment for the target resident fish species (bass, black crappie, bullhead, and carp) will be done using the ingestion rates for these two scenarios with concentration data on each individual resident species (for whole body and fillet tissue). EPCs will be calculated for fishing zones (carp, crappie and bullhead) and mile reach (bass) as well as for the entire Site, as described in Section 3.4.3. In addition to the individual species diet, multiple species diet will also be done for these two fisher groups by using the fish ingestion rates for the scenarios with the concentration data of all resident species (for whole body and fillet tissue) for the Site (i.e., a multiple species diet

assuming that each of the 4 fish target species represents 1/4 of a person's diet). The following scenarios will be evaluated for each of the above ingestion rates.

Programmatic Work Plan April 23, 2004, Appendix C, Section 3.4.3 (p. 25):

Tissue EPCs will be estimated for resident species and for lamprey, salmonids, and sturgeon. The EPCs for lamprey, salmonids, and sturgeon will be used to evaluate risks to Native American consumption fishers in a multiple species diet. The fish consumption evaluation will be based on a range of fish consumption rates. Because these consumption rates will not be designated as representing either RME or CT exposures, the EPCs for tissue will not be developed specifically for RME or CT scenarios. The process to estimate tissue EPCs is described below.

Programmatic Work Plan April 23, 2004, Appendix C, Tables 5-14:

All tables show EPC for RME and CT as TBD.

Discussion: The Programmatic Work Plan states that the risk assessment will evaluate the recreational fisher and high consumption non-tribal (i.e., subsistence) fisher scenarios using the range of fish consumption rates. There is not a 95% UCL/max scenario – this is an incorrect statement in the BHHRA. The agreement was that the EPCs would be discussed in a factual manner and that the terms RME and CT will not be used in reference to the EPCs. However, the BHHRA needs to evaluate the risk and hazards to a reasonable maximum exposure scenario for the two fisher scenarios discussed. Thus, the BHHRA must describe all values that are used in the evaluation of the RME. The EPCs for the RME must be consistent with EPA's guidance, thus the 95% UCL on mean or maximum, if insufficient data or 95% UCL on mean exceeds maximum detected value, must be used in this evaluation. EPA made this clear in the July 16, 2010 comments. The BHHRA must clearly describe this process and EPA modified the language to accurately describe the process used to evaluate the RME and CT.

Our June 22, 2012 letter stated that EPA is requiring the removal of the CT evaluations for the consumption scenarios in the BHHRA. The reason for this is that it was confusing to have a CT consumption rate of 17.5 g/day in one evaluation using an EPC calculated from the 95% UCL on mean or maximum detected concentration and then 3 additional evaluations of CT based on 3 ingestions rates (2 RME and 1 CT) and an average concentration. This is inconsistent with our prior agreements since it was clear that they could include a CT on average EPCs.

Proposed Resolution: EPA has modified the language to clearly discuss the evaluation of the recreational and subsistent fisher RME. The LWG can include the CT based on average in an appendix and provide an uncertainty discussion based on this information.

Dispute Issue #2b (Table 1)

EPA June 22, 2011 letter:

The reference to RME and CT in the BHHRA were not consistent with those agreed to in the Programmatic Work Plan. EPA has had to modify the document to reflect those agreements.

Programmatic Work Plan April 23, 2004, Appendix C, Section 3.5.1.4 (p. 32-33):

Resident Fish Species

Site-specific fish consumption information is not available for the recreational fisher or high consumption non-tribal fisher scenarios. Therefore, to evaluate the potential range in consumption patterns that may exist for these receptors, 3 ingestion rates will be used to calculate intakes for adults and 3 will be used for children. For adults, the fish ingestion rates that will be used in the HHRA are 17.5 grams per day (g/day), 73 g/day, and 142 g/day. The corresponding rates that will be used for children are 7 g/day, 31 g/day, and 60 g/day. These ingestion rates are anticipated to represent average to high end ranges of fish consumption for these receptors.

Two of these rates, 17.5 g/day and 142 g/day, represent the 90th and 99th percentile ingestion rates for freshwater and estuarine fish and shellfish for individuals (consumers and non-consumers) of age 18 and over in the United States (EPA 2002c). Because these rates are from a national dietary study, they may not be representative of site-specific consumption patterns. The other ingestion rate, 73 g/day, is from a creel study conducted in the Columbia Slough and is the 95 percent upper confidence limit on the average for ingestion of fish where 75 percent of the total fish is consumed (Adolfson 1996). While this study may be more representative of consumption patterns for the Site, the study was limited in scope and the reported ingestion rates were estimated based on numerous assumptions. The uncertainties associated with each of the fish ingestion rates will be discussed in the HHRA.

For the recreational fisher and high consumption non-tribal fisher scenarios, the risk assessment for the target resident fish species (bass, black crappie, bullhead, and carp) will be done using the ingestion rates for these two scenarios with concentration data on each individual resident species (for whole body and fillet tissue). EPCs will be calculated for fishing zones (carp, crappie and bullhead) and mile reach (bass) as well as for the entire Site, as described in Section 3.4.3. In addition to the individual species diet, multiple species diet will also be done for these two fisher groups by using the fish ingestion rates for the scenarios with the concentration data of all resident species (for whole body and fillet tissue) for the Site (i.e., a multiple species diet assuming that each of the 4 fish target species represents 1/4 of a person's diet). The following scenarios will be evaluated for each of the above ingestion rates.

Discussion: See Deficiency #2 and #18. I don't think they understand. They are taking a study of both consumers and non-consumers and citing the consumption rates as being the 95th (17.5 g/day) and 99th percentile (142 g/day). The 99th percentile consumption rate for consumers from the same USDA study the consumption rate for consumers only from this study is 506 g/day. **This risk assessment is about consumers only** – there is no exposure, thus no risk or hazard, to non-consumers of fish from this site. EPA did consider fraction of resident fish consumed from the Study Area in determining the ingestion rates and that is why 142 g/day was selected rather than 506 g/day for a subsistence fisher. Anadromous fish cannot be considered in the risk assessment since any contamination found in the fish tissue cannot necessarily be tied to the Site because the range of the fish is beyond that of the Study Area. Whole body fish were assessed for the Asian-Pacific Island subpopulation and fillet with skin were assessed for the remainder of the subsistence fisher population. Since there have not been any studies conducted regarding the reduction of contamination in consumable fish portions of resident fish due to preparation and cooking, the risk assessment could not account for this, but it is appropriate to discuss in an uncertainty discussion. It should be noted, however, that it is not known whether preparation and cooking would decrease, increase, or transform (e.g., PCBs transform to dioxins when heated) contaminants in tissue, so all of these plausibilities should be discussed in the uncertainty.

Likewise, the rate of 17.5 g/day (equivalent to two 8-ounce meals per month) is based on the 90th percentile rate for uncooked freshwater and estuarine finfish and shellfish for individuals (consumers and non-consumers) of age 18 and over in the United States (EPA 2002b, data from USDA CSFII Study). The 90th percentile for fish consumers only from this USDA study is much higher, at 200 g/day. EPA uses the 17.5 g/day rate to approximate a fish-consuming population that does not include tribal or subsistence fishers. This ingestion rate actually approximates a central tendency for fish consumers rather than an upper percentile, as necessary for an RME. EPA has determined that the non-tribal adult fish consumption rate of 73 g/day that was used in this risk assessment based on data from the Columbia Slough is supported by the USDA study as an appropriate rate as the RME for a recreational fisher.

Since the ingestion rate of 17.5 g/day is a central tendency for consumption of fish, it did not make sense to retain the evaluations of central tendency for fish consumption based on the arithmetic mean calculations, so EPA has required that they be removed from the BHHRA.

EPA understands that the Programmatic Work Plan allowed for calculations based on the arithmetic mean for the EPC, even though this is inconsistent with our guidance.

EPA Guidance (RAGS A) Page 6-19, Exposure concentration, 2nd paragraph.

> *Because of the uncertainty associated with any estimate of exposure concentration, the upper confidence limit (i.e., the 95 percent upper confidence limit) on the arithmetic average **will be** used for this variable.*

Consequently, EPA will not consider the central tendency evaluations based on arithmetic mean of the EPC in the BHHRA determining appropriate cleanup actions at this site.

Proposed Resolution: EPA has revised language in BHHRA to better explain this issue and define the RME and CT according to consumption rates.

Dispute Issue #3

EPA June 22, 2011 letter:

There were many instances in the BHHRA where the only explanation the LWG provides for why something is done was that EPA directed or otherwise required it be done. While it may be true EPA directed changes, the LWG is fully aware of the technical basis for the direction and should have included such technical basis in the report. The LWG's failure to fully explain the basis for how the risk assessment was done is not consistent with EPA guidance nor is the report complete and transparent without it. Therefore, EPA had to modify the report to provide the rational for the directions in the text of the BHHRA for clarity and relevance for the assessment.

Discussion: EPA has modified the document to clearly and factually state the basis for the BHHRA risk assessment process. The basis goes beyond the issue of EPA directing the LWG to do it. EPA has always provided rational for making such requirements and the rational was not provided in the BHHRA. By simply stating that something was done because EPA required it makes the requirement appear arbitrary and capricious and does not provide the basis or grounds for the requirement.

Proposed Resolution: The record clearly shows EPA's comments and direction. It is not clear why the LWG believes this was important to note in some instances where EPA gave direction, but not in all instances. However, EPA would not be opposed to the LWG providing footnotes to issues they believe are important to note that were at EPA direction. The footnote should include all references where the direction was provided to the LWG. If approach is acceptable, specific language and location in BHHRA would have to be developed and agreed to by both parties.

Dispute Issue #4

EPA June 22, 2012 letter:

Overall, the BHHRA did not present the process and information in a clear and transparent manner that would allow anyone outside those intimately involved in the development of this assessment to follow and understand. Thus, EPA had to extensively modify the report to make the report understandable to the general public.

EPA July 21, 2011 letter:

This letter is requesting copies of files used to develop the draft Baseline Human Health Risk Assessment (BHHRA) for the Portland Harbor Superfund Site submitted to the EPA on May 2, 2011. EPA appreciates the significant amount of work that the LWG has put into this document. From our review to date, EPA agrees with the numerical calculations and technical findings of the document; however, the document does not satisfactorily address all of EPA's comments, and lacks sufficient clarity presenting the process and conclusions in a clear and transparent manner. Under the AOC, Section IX.1., EPA has the right to modify any deliverables under the AOC, which EPA intends to do with the BHHRA. Consequently, EPA is requesting all the original document (Word, Excel, etc.) files used to create the BHHRA so that we can modify the document.

Discussion: EPA agrees with the LWG that this is a new comment. EPA's decision to revise the document was not a basis for determining the LWG was not in compliance with the AOC. The LWG has followed the agreed upon process to conduct the BHHRA under the AOC. In July 2010, EPA notified the LWG that the BHHRA did not satisfactorily address all EPA's comments and lacks sufficient clarity presenting the process and conclusions. Since the LWG submittal of the Draft BHHRA on May 2, 2011, EPA has also received a white paper from a group of 45 Portland Harbor PRPs *Risk Management Decisions Required* (October 2011) and a congressional inquiry (November 23, 2011) that both clearly indicated to EPA that the Draft BHHRA did not provide a clear, concise, and transparent discussion of the process used to conduct the BHHRA. EPA has not changed the process used by the LWG under the AOC to conduct the BHHRA, but only provided revisions meet provides a document that clearly, concisely, and transparently describes the BHHRA process. In many instances, original text was only moved to a new location or was removed because it was redundant. EPA took on the task of accomplishing this since there has been many complaints regarding the schedule of this project and EPA was expediting the process by providing the LWG with a document that EPA could approve.

Proposed Resolution: EPA has revised the BHHRA to clearly and accurately describe the BHHRA process. The LWG has not provided any specific instance where the modification EPA made did not accurately describe the process.

Table 2

Dispute Issue #1

The LWG objects to EPA's revisions that delete factual information regarding clam consumption because these revisions are inconsistent with prior agreements between EPA and LWG.

Discussion: EPA removed language in the BHHRA that was not relevant to the document, whether it was factual or not. It is not relevant that ODFW rules prohibit importation, possession, confinement, transportation and sale of this species. This is considered an institutional control and it is not known to what extent it is actually complied with, especially since EPA has information that there are people eating Asian Clams from the Study Area. The baseline risk assessment is supposed to look at current and potential future uses without consideration of institutional controls. Since there is currently a use of people eating Asian Clams, the assessment needs to evaluate it. This is similar to the fact that even though OHA has a fish advisory for only 1 fish meal per month, the risk assessment did not use that limitation in determining the consumption rates for the BHHRA.

Proposed Resolution: Since this has no bearing on BHHRA, it should not be discussed in the text. However, there could be a footnote included to text [or inserted into text] in Section 3.3.6 that states "Harvest and possession of Asian clams is illegal in the state of Oregon because Asian clams are on the prohibited species list of the ODFW rules regarding the importation, possession, confinement, transportation and sale of nonnative wildlife (OAR 635-056-0050). However, this institutional control has no bearing on the BHHRA because Superfund baseline risks are risks that might exist if no remediation or institutional controls were applied at a site. (RAGs Part A)"

Dispute Issue #2

The LWG objects to EPA's revisions describing the drinking water scenario, including deleting the term "hypothetical", because these revisions are inconsistent with prior agreements between EPA and the LWG.

Discussion: EPA has made changes to the BHHRA to make it more in line with EPA's Human Health Risk Guidance (RAGS A) which requires the evaluation of ***potential*** environmental effects at the site.

The word potential (adj.) means: 1) existing in possibility : capable of development into actuality, 2) expressing possibility; specif : of, relating to, or constituting a verb phrase expressing possibility, liberty, or power by the use of an auxiliary with the infinitive of the verb (as in "it may rain").

The word hypothetical (adj.) means: 1) being or involving a hypothesis : conjectural, 2) inference from defective or presumptive evidence, 3) a conclusion deduced by surmise or guesswork.

It is clear from these definitions that ***potential*** and ***hypothetical*** do not have the same meaning, thus, EPA should never have allowed the use of the word in the BHHRA. To do so only makes the assessment of this exposure scenario seem unrealistic. Since the water quality standards for the Lower Willamette River identify domestic water supply as a designated beneficial use (OAR 340-041-0340 Table 340A), it is a reasonable likely future use of this river.

It is not clear why the LWG is insisting on the use of this word in the context of this scenario and not in other scenarios (e.g., clam consumption). Why does this matter so much to them?

Proposed Resolution: The word "hypothetical" can be used once in Section 6.2.3.4, but not in title.

Dispute Issue #3

The LWG objects to EPA's revisions deleting references to evaluations being done at the direction of EPA because these revisions are inconsistent with prior agreements between EPA and the LWG.

Discussion: EPA has modified the document to clearly and factually state the basis for the BHHRA risk assessment process. The basis goes beyond the issue of EPA directing the LWG to do it. EPA has always provided rational for making such requirements and the rational was not provided in the BHHRA. By simply stating that something was done because EPA required it makes the requirement appear arbitrary and capricious and does not provide the basis or grounds for the requirement.

Proposed Resolution: The record clearly shows EPA's comments and direction. It is not clear why the LWG believes this was important to note in some instances where EPA gave direction, but not in all instances. However, EPA would not be opposed to the LWG providing text or footnotes to issues they believe are important to note that were at EPA direction. The text or footnote should include all references where the direction was provided to the LWG. If approach is acceptable, specific language and location in BHHRA would have to be developed and agreed to by both parties.

Dispute Issue #4

The LWG objects to EPA's revisions that modify the Study Area boundaries because these revisions are inconsistent with prior agreements between EPA and the LWG.

Discussion: The revisions to the Study Area boundary were only intended to clarify the language and make consistent with the data collected.

Proposed Resolution: The language describing the study area can be changed to

Section 1.3 “The approximate 10-mile portion of Portland Harbor from RM 1.9 to 11.8 is referred to as the Study Area (Map 1-1). Data used for this risk assessment was collected from RM 0.8 to RM 12.2.”

Dispute Issue #5

The LWG objects to EPA’s revisions that were not the subject of prior comments.

Discussion:

Executive Summary section deleted.

EPA deleted the Executive Summary from the BHHRA because it is now an appendix to the RI. An appendix does not need an executive summary if the information is discussed in the body of the document to which it is an appendix, which is the case here. The section of the RI regarding the BHHRA will be the executive summary for this document.

Conclusions section deleted.

Conclusions from the LWG’s draft BHHRA are combined with conclusions in Section 5. EPA did not see the need to repeat the conclusions.

Proposed Resolution: The LWG can retain its right to object to the content of the RI serving as the executive summary until EPA provides the revisions to the RI at a later date.